

Pennsylvania Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 390111	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____		(X3) DATE SURVEY COMPLETED: 05/22/2023
NAME OF PROVIDER OR SUPPLIER: PENN MEDICINE RADNOR SURGERY CENTER STATE LICENSE NUMBER: 16751501		STREET ADDRESS, CITY, STATE, ZIP CODE: 145 KING OF PRUSSIA ROAD Suite G-104 RADNOR, PA 19087			
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S 0110	Continued from page 1 551.21 (e)(1-3) Criteria for ambulatory surgery 551.21 Criteria for ambulatory surgery (e) In obtaining informed consent, the practitioner performing the surgery shall be responsible for disclosure of: (1) The risks, benefits and alternatives associated with the anesthesia which will be administered. (2) The risks, benefits and alternatives associated with the procedure which will be performed. (3) The comparative risks, benefits and alternatives associated with performing the procedure in the ambulatory surgical facility instead of in a hospital. This REGULATION is not met as evidenced by:	S 0110	The Penn Medicine Radnor Surgery Center, a facility of the Hospital of the University of Pennsylvania (RSC), took prompt steps to require that physician anesthesia staff who personally perform or medically direct the administration of anesthesia for surgical procedures in the RSC alter their process for consenting patients whenever there is a need to change the type of anesthesia preoperatively prior to the administration of any sedative medication. The RSC is taking the following measures to prevent reoccurrence: The certified registered nurse anesthetist (CRNA), and/or anesthesiologist, and the circulating nurse (RN) will conduct an anesthesia time-out in the operating/procedure room prior to the administration of any sedation during which the plan for anesthesia will be confirmed with the patient and the circulating RN will confirm that the planned anesthetic is consistent with what is documented	Completion Date: 07/31/2023 Status: APPROVED Date: 06/23/2023	

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S 0110	Continued from page 2	S 0110	<p>on the signed consent form.</p> <p>- The current anesthesia consent form was reviewed by the RSC Director of Anesthesia on May 24, 2023 and it was determined that the language sufficiently explains the process when there is a need to advance to a higher level of anesthesia care during a procedure and that this is discussed with the patient and/or legally authorized representative prior to them signing the consent form.</p> <p>- If there is a need to alter the anesthesia plan documented on the anesthesia consent form prior to the administration of anesthesia a hard stop will occur and a new consent form will be completed by the patient, or their legally authorized representative, prior to proceeding.</p> <p>- If a patient is unable to sign their own consent form, the anesthesiologist will leave the Operating/ Procedure room and discuss the change in anesthesia plan with the patient's legally authorized representative, at which time a new consent form will be</p>		

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S 0110	Continued from page 3	S 0110	<p>completed and signed.</p> <ul style="list-style-type: none">- In the unanticipated event that the anesthesia plan needs to be changed for the patient's safety during the procedure, following the initiation of anesthesia, the anesthesiologist will document the reason for the change in the electronic medical record (EMR).- The RSC Anesthesia Director will train, via email with read receipt or a signed attestation, all anesthesiologists and CRNAs on the correct process to obtain and document informed consent for the planned anesthesia as well as the process to be followed if the anesthesia plan must be changed prior to the administration of anesthesia. This will be completed by July 31, 2023.- By July 31, 2023, anesthesia providers and perioperative nurses will participate in re-education, given by RSC leadership, on the proper procedure for conducting and participating in the anesthesia time-out and will sign an attendance record.		

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S 0110	Continued from page 4	S 0110	The RSC will monitor its performance by the following: - Ten (10) weekly randomized audits of the EMR will be conducted by the RSC Administrator or designee to review the anesthesia consents for surgical procedures. - The RSC Administrator or designee will audit the anesthesia consents for a determination of whether the consent that has been signed by the patient or legally authorized representative matches the anesthesia type that was given during the procedure. If there is not a match, the RSC Administrator or designee will then audit the documentation for the reason that the consent and anesthesia provided during the procedure were not matching. - The RSC Administrator or designee will monitor compliance and notify, via email with Read Receipt, the Anesthesia Director and Medical Director of any discrepancies. - The Anesthesia Director and/or Medical Director will review the discrepancy with the respective		

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S 0110	Continued from page 5	S 0110	anesthesia provider. - Auditing of compliance will be monitored by the RSC Administrator or designee until a period of three consecutive months with 100% compliance is achieved. - Compliance results will be reviewed by the RSC Patient Safety Committee and the RSC Quality Assurance Performance Improvement (QAPI) Committee quarterly to demonstrate sustained compliance as part of the ongoing quality assurance and performance improvement activities. Completion date for Plan of Correction is July 31, 2023. Title of person responsible for compliance: RSC Administrator and the RSC Medical Director		

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S 0110	<p>Continued from page 6</p> <p>Based on a review of facility policy, medical records (MR) and interview with staff (EMP), it was determined the facility failed to ensure informed consent was obtained by the provider for the type of anesthesia to be administered during the surgical procedure in three of ten medical records reviewed (MR1, MR6 and MR10).</p> <p>Findings include:</p> <p>A review of facility policy "Consent to Health Care Services" dated December 13, 2021, revealed "Scope. This policy applies to the Hospital of the University of Pennsylvania (HUP)... and those ambulatory surgical facilities operating under HUP's governing body when clearly indicated, including Penn Medicine Radnor Surgery Center... Implementation. All HUP/CPUP (Clinical Practices of the University of Pennsylvania) staff including ...individual care givers and providers rendering care, are responsible for the implementation of this policy. ...C. Special Circumstances: 1. Administration of Anesthesia Associated with</p>	S 0110			

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S 0110	<p>Continued from page 7</p> <p>Operative and Invasive Procedures: Unless delegated to another qualified practitioner, an attending anesthesiologist staffing the operative/procedural service during a patient's admission must obtain informed consent for anesthesia care and procedures associated with operative and invasive procedures that may be performed by them and by other attending anesthesiologists, CRNA's (certified registered nurse anesthetist) or residents/fellows under the anesthesiologists' supervision..."</p> <p>A review on April 17, 2023, of MR1, admitted August 24, 2022, for a colonoscopy procedure under monitored anesthesia care (MAC anesthesia) revealed a "Consent for Anesthesia, Monitoring and Related Special Procedures" form signed by the patient and attending anesthesiologist. Further review revealed "Types and Risks of Anesthesia: Anesthesia involved risks in addition to the risks of the procedure itself. The particular type of anesthesia planned for your procedure and the associated risks have been discussed with you as</p>	S 0110			

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S 0110	<p>Continued from page 8</p> <p>indicated below... Your anesthesiologist plans to perform the following peripheral nerve block(s): Peripheral nerve blocks involve injection of medication near one or more nerves to temporarily numb a specific area of the body." Further review of MR1 revealed an "Anesthesia Preprocedure Evaluation" note authored by CF1, on August 24, 2022, at 2:03 PM, revealed "Anesthesia Plan... Anesthesia type: MAC... Anesthesia consent obtained."</p> <p>A review on April 17, 2023, of MR6, admitted March 17, 2023, for a breast implant procedure under general anesthesia revealed a "Consent for Anesthesia, Monitoring and Related Special Procedures" form signed by the patient and attending anesthesiologist. Further review revealed "Types and Risks of Anesthesia: Anesthesia involved risks in addition to the risks of the procedure itself. The particular type of anesthesia planned for your procedure and the associated risks have been discussed with you as indicated below... Monitored Anesthesia Care (MAC) or monitored</p>	S 0110			

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S 0110	<p>Continued from page 9</p> <p>sedation involves the use intravenous medication to calm you, to make you less aware of the procedure and to increase the effectiveness of medications that may be injected to temporarily numb the area to be operated on by the surgeon." Further review of MR6 revealed an "Anesthesia Preprocedure Evaluation" note authored by CF2, March 17, 2023, at 8:10 AM, revealed "Anesthesia plan... Anesthesia type: general ...Anesthesia consent obtained."</p> <p>A review on April 18, 2023, of MR10, admitted February 20, 2023, for a posterior neck lipoma excision procedure under general anesthesia revealed a "Consent for Anesthesia, Monitoring and Related Special Procedures" form signed by the patient and attending anesthesiologist. Further review revealed "Types and Risks of Anesthesia: Anesthesia involved risks in addition to the risks of the procedure itself. The particular type of anesthesia planned for your procedure and the associated risks have been discussed with you as indicated below... Monitored Anesthesia Care</p>	S 0110			

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S 0110	<p>Continued from page 10</p> <p>(MAC) or monitored sedation involves the use intravenous medication to calm you, to make you less aware of the procedure and to increase the effectiveness of medications that may be injected to temporarily numb the area to be operated on by the surgeon." Further review of MR10 revealed an "Anesthesia Preprocedure Evaluation" note authored by CF2 dated February 20, 2023, at 10:44 AM, revealed "Anesthesia plan... Anesthesia type: general ...Anesthesia consent obtained."</p> <p>An interview conducted April 17, 2023, at 3:52 PM with EMP8 confirmed the type of anesthesia written on the signed informed consent form for MR1, MR6 and MR10 was incorrect.</p> <p>An interview conducted April 18, 2023, at 11:11 AM with EMP6, who stated "The anesthesiologist should confirm the signed consent form has the correct information. in the document and then patient and doctor can sign."</p>	S 0110			

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S 033A	Continued from page 12 553.3 (1) Governing Body Responsibilities 553.3 Governing Body responsibilities include: (1) Conforming to all applicable Federal, State, and local laws. This REGULATION is not met as evidenced by:	S 033A	The Penn Medicine Radnor Surgery Center, a facility of the Hospital of the University of Pennsylvania (RSC) took prompt steps to report an event that was deemed to be a serious event by the Pennsylvania Department of Health Surveyor on April 17, 2023 during the annual licensure survey. The RSC leadership team, in collaboration with the Penn Medicine Risk Management department and the Pennsylvania Patient Safety Authority Liaison, reviewed the event and determined that this event met criteria for reporting as a serious event. The Serious Event was reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) on April 17, 2023. The RSC is taking the following measures to prevent reoccurrence: The RSC Patient Safety Officer (PSO) and/or designee will review all safety events for the RSC to determine the severity of the event in addition to reviewing the reporting algorithm that was provided by the Pennsylvania Patient Safety	Completion Date: 07/31/2023 Status: APPROVED Date: 06/23/2023	

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S 033A	Continued from page 13	S 033A	<p>Authority (PSA) on April 18, 2023. The PSO will utilize the algorithm as a guideline for reporting in the future. The PSO will discuss potential serious events with the Risk Management department using the Patient Safety Algorithm in determining the severity of the event and whether the event meets criteria for reporting to PA-PSRS.</p> <ul style="list-style-type: none"> - The PSO has established a working relationship with the PSA Senior Patient Safety Liaison. - RSC leadership – Administrator, Nursing Director and Medical Director - will complete re-training on occurrence reporting through Penn Medicine on line education module "Penn Medicine Safety Event Reporting" by July 31, 2023 - Intra-operative transfers from the RSC to a hospital, where a procedure and/or anesthesia has been initiated in the operating/ procedure room, will be reported as a serious event through PA-PSRS. - The PSO and/or a representative from the Risk Management department will reach out to the 		

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S 033A	Continued from page 14	S 033A	<p>Patient Safety Authority liaison to discuss ambiguous events to assess whether they need to be reported to PA-PSRS.</p> <ul style="list-style-type: none"> - The PSO will work with Penn Medicine Risk Management so that events are reported appropriately and in accordance with Act 13 of 2202, Medical Care Availability and Reduction of Error (MCARE), Department of Health and PSA requirements. - The RSC will monitor its performance by the following: <ul style="list-style-type: none"> - Auditing of all patient transfers will be conducted quarterly to ensure that events are appropriately reported. - Serious events will be reviewed, discussed and recommendations made as needed at the RSC Patient Safety Committee - The PSO and/or designee will monitor safety events and notify the RSC Medical Director of any serious events. - Compliance will be reviewed by the RSC Patient Safety Committee and the RSC Quality Assurance 		

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S 033A	Continued from page 15	S 033A	Performance Improvement (QAPI) Committee quarterly to demonstrate sustained compliance as part of the ongoing quality assurance and performance improvement activities. Completion date for Plan of Correction is July 31, 2023. Title of person responsible for compliance: RSC Administrator and RSC Medical Direct		

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S 033A	<p>Continued from page 16</p> <p>Based on a review of facility documents, medical records (MR) and interview with staff (EMP), it was determined the facility was not in compliance with the following State Law.</p> <p>The Penn Medicine Radnor Surgery Center was not in compliance with the following State law related to Act 13 2002, Medical Care Availability and Reduction of Error (MCARE) Act 40 PS. Chapter 3 Patient Safety. Section 301 "Serious event." An event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient.</p> <p>...Section 313: Medical facility reports and notifications. (a) Serious event reports.--A medical facility shall report the occurrence of a serious event to the department and the authority within 24 hours of the medical facility's confirmation of the occurrence of the serious event. The report to the department and the authority shall be in the form and manner prescribed by the authority in consultation</p>	S 033A			

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S 033A	<p>Continued from page 17</p> <p>with the department and shall not include the name of any patient or any other identifiable individual information.</p> <p>This is not met as evidenced by:</p> <p>Based on a review of facility documents, medical records (MR) and interview with staff (EMP), it was determined that the facility failed to provide notification to the Pennsylvania Department of Health, the ("Department") as required in one of two medical records reviewed (MR1).</p> <p>Findings include:</p> <p>A review of the Penn Medicine Radnor Surgery Center "Patient Safety Plan" last revised March 28, 2023, revealed "The Hospital of the University of Pennsylvania (HUP) Ambulatory Surgical Facility Coordinating Committee and the HUP Board of Trustees, the governing body for the ambulatory surgical facility known as the Penn Medicine Radnor Surgery Center ...(RSC) is committed to creating an environment within the RSC that encourages error</p>	S 033A			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 390111	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____		(X3) DATE SURVEY COMPLETED: 05/22/2023
NAME OF PROVIDER OR SUPPLIER: PENN MEDICINE RADNOR SURGERY CENTER STATE LICENSE NUMBER: 16751501		STREET ADDRESS, CITY, STATE, ZIP CODE: 145 KING OF PRUSSIA ROAD Suite G-104 RADNOR, PA 19087			
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S 033A	Continued from page 18 identification, remediation, non-punitive reporting... Full disclosure of serious medical errors or unanticipated outcomes will be made to patients/families and to accrediting and licensing bodies as appropriate. ...II. Definition of Terms ...Serious event, as defined by PA PSRS (Pennsylvania Patient Safety Reporting System) program, is an event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient. ...D. Notification of Regulatory, Licensing and Accrediting Agencies. A serious event or incident will be reported to regulatory, licensing and/or accrediting agencies, if appropriate, within the applicable time period after consultation with the Penn Medicine Office of the General Counsel. These agencies may include, but not be limited to, the Pennsylvania Department of Health and the Pennsylvania Patient Safety Authority." A review on April 17, 2023, of MR1, admitted	S 033A			

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S 033A	<p>Continued from page 19</p> <p>August 24, 2022, for a colonoscopy procedure under monitored anesthesia care (MAC) revealed MR1 developed a cardiac arrhythmia immediately after the induction of MAC anesthesia. MR1 was subsequently transferred to a local hospital for additional health care services.</p> <p>A request was made on April 17, 2023, at 9:25 AM to EMP7 for documentation of the facility report to the "Department" for the serious event of the unanticipated injury requiring the delivery of additional health care services for MR1. No documentation was provided.</p> <p>An interview conducted on April 17, 2023, at 9:30 AM with EMP7 confirmed MR1 experienced an unanticipated injury immediately after the induction of MAC anesthesia that required the delivery of additional health care services. EMP7 further confirmed the event was not reported to the "Department" through the Pennsylvania Patient Safety Authority as a serious event. EMP7 stated "We did not realize we had to report it."</p>	S 033A			

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S 033A	Continued from page 20	S 033A			
S 5200		S 5200			

Pennsylvania Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 390111	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____		(X3) DATE SURVEY COMPLETED: 05/22/2023
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S 5200	Continued from page 21 555.2 Medical staff membership 555.2 Medical Staff Membership A member of the medical staff shall be qualified for membership and the exercise of clinical privileges granted to him. The governing body of the ASF, after considering the recommendations of the medical staff, may grant clinical privileges to qualified, licensed practitioners in accordance with their training, experience and demonstrated competence and judgement. Members of the medicals staff and others granted clinical privileges shall currently hold licenses to practice in this Commonwealth. This REGULATION is not met as evidenced by:	S 5200	The Penn Medicine Radnor Surgery Center , a facility of the Hospital of the University of Pennsylvania (RSC) is taking the following measures to prevent reoccurrence: The clinical privileges of all Surgeons, Endoscopists, and Anesthesiologists credentialed at the Penn Medicine Radnor Surgery Center have been reviewed and where applicable no longer include the following privilege: "Placement and Management of arterial lines, central venous lines, dialysis catheters, with or without image guidance". - On April 18, 2023, RSC leadership communicated with the Hospital of the University of Pennsylvania (HUP) Office of Medical Affairs (OMA) requesting the removal of the following privilege from the Radnor Surgery Center delineation of privileges form "Placement and Management of arterial lines, central venous lines, dialysis catheters, with or without image guidance". - On April 18, 2023, the Chair of the Department of Surgery for HUP	Completion Date: 07/31/2023 Status: APPROVED Date: 06/23/2023	

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S 5200	Continued from page 22	S 5200	<p>approved the removal of this privilege.</p> <p>- On April 19, 2023, the HUP Medical Staff Credentials and Practitioner Review Committee approved the recommendation of removing the following privilege from the Radnor Surgery Center delineation of privileges form: "Placement and Management of arterial lines, central venous lines, dialysis catheters, with or without image guidance".</p> <p>- On April 24, 2023, the HUP Board of Trustees, through its Executive Committee, approved the recommendation from the HUP Credentials and Practitioner Review Committee to remove the specified privilege.</p> <p>- On April 24, 2023, the privilege "Placement and Management of arterial lines, central venous lines, dialysis catheters, with or without image guidance" was removed from the RSC delineation of privileges form.</p> <p>- The RSC Administrator and RSC Medical Director will review the delineation of privileges form for</p>		

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S 5200	Continued from page 23	S 5200	<p>each approved specialty in the RSC and will compare the list of approved procedures to verify that providers do not have the option to select a procedure that is not approved to be performed at the RSC by July 31, 2023.</p> <p>- Removal of privileges will require written notification to the privileged provider involved and including notification of the updated privileges granted/ approved for these practitioners.</p> <p>Plan:</p> <p>- When providers are requesting privileges at the RSC, the delineation of privileges form will be sent to the RSC Medical Director and RSC Administrator for their review to determine accurateness.</p> <p>- The RSC Medical Director and RSC Administrator will verify that all requested privileges align with approved procedure list on the form.</p> <p>- The RSC Medical Director will sign off on the privilege request, verifying that requested privileges fall within the approved scope of the license granted to the facility by the</p>		

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S 5200	Continued from page 24	S 5200	<p>Pennsylvania Department of Health.</p> <p>The RSC will monitor its performance by the following:</p> <ul style="list-style-type: none">- Three (3) monthly audits of the Penn Medicine privileges webpage will be conducted by the RSC Administrator or designee to review the privileges of existing providers.- The RSC Administrator or designee will monitor compliance and notify the RSC Medical Director and the Office of Medical Affairs of any discrepancies and the recommended correction needed.- Auditing of compliance will be monitored by the RSC Administrator or designee until a period of three consecutive months with a compliance rate of 100% is achieved.- Compliance results will be reported to the HUP Medical Board (Medical Executive Committee), the RSC Quality Committee and the HUP Board of Trustees' ASF Coordinating Committee quarterly to demonstrate sustained compliance as part of the ongoing quality assurance and performance		

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S 5200	Continued from page 25	S 5200	improvement activities. Completion date for Plan of Correction is July 31, 2023. Title of person responsible for compliance: RSC Administrator and RSC Medical Director		

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S 5200	<p>Continued from page 26</p> <p>Based on review of facility Bylaws, credential files (CF) and interview with staff (EMP), it was determined the Board of Trustees (governing body) and facility Medical Staff failed to ensure clinical privileges that were granted to qualified medical providers were limited to the scope of the license granted to the facility by the "Department" for four of six credential files reviewed (CF3, CF4, CF5, and CF6).</p> <p>Findings include:</p> <p>Review of the facility's "Medical Staff Bylaws: Component Medical Staff Organization And Functions Manual Of The Hospital Of The University Of Pennsylvania" last revised January 25, 2023, revealed "This Policy on Appointment, Reappointment, and Clinical Privileges has been created pursuant to and as a component of the Medical Staff Bylaws of the Hospital of the University of Pennsylvania of the University of Pennsylvania Health System, a clinical component of Penn Medicine. The purpose of this Policy is to</p>	S 5200			

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S 5200	<p>Continued from page 27</p> <p>describe the credentialing process that will be followed for Medical Staff applicants and Appointees, including: initial appointment, clinical privileges, reappointment, questions pertaining to Medical Staff Appointees, and hearings and appeals.Article 1-DEFINITIONS AND GENERAL PROVISIONS ... Ambulatory Surgical Facility(ies) " means thethe Penn Medicine Radnor Surgery Center, a facility of the Hospital of the University of Pennsylvania (" RSC "), and all such other ambulatory surgical facilities that are or may be owned or operated by the Hospital that are licensed as ambulatory surgical facilities. These Medical Staff Bylaws and Accompanying Manuals apply to each such Ambulatory Surgical Facility..2.D Clinical Privileges ... The criteria for evaluating the qualifications for delineated clinical privileges shall be developed by each Department Chair subject to the approval of the Credentials and Practitioner Review Committee which shall resolve any differences and inconsistencies ... "</p> <p>Review on April 17, 2023, of CF3, a physician,</p>	S 5200			

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S 5200	Continued from page 28 specialty "Plastic Surgery" revealed CF3 received approval for privileges "Placement and Management of Arterial Lines, Central Venous Lines, Dialysis Catheters" by the Medical Staff Reviewer on June 23, 2021, and the Chair on June 25, 2021. Further review revealed the Board of Trustee of the Hospital (governing body) approved a two-year reappointment period with privileges granted for "Placement and Management of Arterial Lines, Central Venous Lines, Dialysis Catheters " from August 1, 2021, through July 31, 2023. Review on April 17, 2023, of CF4, a physician, specialty "Plastic Surgery" revealed CF4 received approval for privileges "Placement and Management of Arterial Lines" by the Medical Staff Reviewer on November 8, 2022, and the Chair on November 10, 2022. Further review revealed the Board of Trustee of the Hospital (governing body) approved a two-year appointment period with privileges granted for "Placement and Management of Arterial Lines, Central Venous Lines, Dialysis Catheters" from December 1, 2022, through November 30,	S 5200			

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S 5200	<p>Continued from page 29</p> <p>2024.</p> <p>Review on April 17, 2023, of CF5, a physician, specialty "Plastic Surgery" revealed CF5 received approval for privileges "Placement and Management of Arterial Lines" by the Chair of the Medical Staff on 12/11/2021. Further review revealed the Board of Trustee of the Hospital (governing body) approved a two-year reappointment period with privileges granted for "Placement and Management of Arterial Lines, Central Venous Lines, Dialysis Catheters " from January 1, 2023, through December 31, 2024.</p> <p>Review on April 17, 2023, of CF6, a physician, specialty "Plastic Surgery" revealed CF6 received approval for privileges " Placement and Management of Arterial Lines, Central Venous Lines, Dialysis Catheters" by the Medical Staff Reviewer on January 18, 2023, and the Chair on January 20, 2023. Further review revealed the Board of Trustee of the Hospital (governing body) approved a two-year reappointment period with</p>	S 5200			

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S 5200	Continued from page 30 privileges granted for "Placement and Management of Arterial Lines, Central Venous Lines, Dialysis Catheters " from April 1, 2023, through March 31, 2025. An interview conducted on April 17, 2023, at 1:15 PM with EMP7 and EMP14 confirmed CF3, CF4, CF5 and CF6 was granted privileges for 2-year appointment/reappointment periods with privileges for "Placement and Management of Arterial Lines, Central Venous Lines, Dialysis Catheters by the Board of Trustee (governing body) and approved by the Medical Staff. EMP7 stated " We do not do those procedures at the surgery center. I know we are not licensed by the "Department" to do those type of procedures here. "	S 5200			
S 552E		S 552E			

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S 552E	Continued from page 31 555.22 (e) Surgical Services - Preoperative 555.22 Pre-operative Care (e) Prior to the administration of anesthesia, it is the responsibility of the primary operating surgeon and the person administering anesthesia to properly identify the patient and the procedure to be performed and to document this identification in the patient's medical record. This procedure shall be in written policies designating the mechanism to be used to identify each surgical patient. This REGULATION is not met as evidenced by:	S 552E	The Penn Medicine Radnor Surgery Center, a facility of the Hospital of the University of Pennsylvania (RSC) took prompt steps to verify that the identification of the patient is obtained by all proceduralists prior to the administration of an anesthetic. The administration of anesthesia is considered the start of the procedure. The RSC is taking the following measures to prevent reoccurrence: The physician/proceduralist performing the procedure will document in the Electronic Medical Record (EMR) that they have identified the patient prior to the administration of an anesthetic. In particular, the physician will write and sign a note in the EMR confirming that they have identified the patient. This note will contain a date and time that the identification occurred. - The RSC Medical Director will communicate, via email with read receipt or a signed attestation, to all surgeons/ proceduralists reiterating the importance of documenting in	Completion Date: 07/31/2023 Status: APPROVED Date: 06/23/2023	

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S 552E	Continued from page 32	S 552E	the EMR that they identified the patient prior to the administration of an anesthetic. - Additionally, if a procedure is cancelled for medical reasons after the patient has entered an operating/procedure room, but prior to the start of the intended procedure, the EMR must contain a note that the patient had been identified if any anesthetic has been given. - Intra-operative transfers from the RSC to a hospital, where a procedure and/or anesthesia has been initiated in the operating/ procedure room, will be reported as a serious event through PA-PSRS. - The certified registered nurse anesthetist (CRNA), and/or anesthesiologist, and the circulating nurse (RN) will conduct an anesthesia time-out in the operating/procedure room prior to the administration of any sedation during which the patient identity will be confirmed with the patient. The RSC will monitor its performance by the following:		

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S 552E	Continued from page 33	S 552E	<ul style="list-style-type: none"> - Ten (10) weekly audits of the EMR will be conducted by the RSC Administrator or designee to verify compliance in certification of patient identity prior to the administration of anesthesia. - The RSC Administrator or designee will monitor compliance and notify the RSC Medical Director of any discrepancies. - Auditing of compliance will be monitored by the RSC Administrator or designee until a period of three consecutive months with a compliance rate of 100% is achieved. - Compliance results will be reported to the HUP Medical Board (Medical Executive Committee), the RSC Quality Committee and the HUP Board of Trustees' ASF Coordinating Committee quarterly to demonstrate sustained compliance as part of the ongoing quality assurance and performance improvement activities. <p>Completion date for Plan of Correction is July 31, 2023. Title of person responsible for compliance: RSC Administrator and RSC Medical Director</p>		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 390111	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____		(X3) DATE SURVEY COMPLETED: 05/22/2023
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S 552E	<p>Continued from page 34</p> <p>Based on a review of facility policy, medical record review (MR), and interview with staff (EMP), it was determined the facility failed to ensure proper identification of the patient was obtained by the surgeon prior to the administration of anesthesia as required by the Department of Health (the "Department") in one of one medical records reviewed (MR1).</p> <p>Findings include:</p> <p>A review of facility policy "Anesthesia Time Out," undated, revealed "POLICY It is the policy of the Penn Medicine Radnor Surgery Center, a facility of the Hospital of Pennsylvania (RSC) that an anesthesia time out procedure is performed prior to any procedure. ...DEFINITIONS Time Out is an immediate pause by the entire surgical/procedural team to confirm patient identity, procedure, and site."</p> <p>A review on April 17, 2023, of MR1, admitted August 24, 2022, for a colonoscopy procedure</p>	S 552E			

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S 552E	<p>Continued from page 35</p> <p>under monitored anesthesia care (MAC) revealed MR1 developed a cardiac arrhythmia immediately after the induction of MAC anesthesia. MR1 was subsequently transferred to a local hospital for additional health care services. Further review revealed there was no documentation that the surgeon identified the patient prior to the administration of anesthesia.</p> <p>An interview conducted on April 17, 2023, at 12:20 PM with EMP13 confirmed there was no documentation that the surgeon identified the patient prior to the administration of anesthesia. EMP13 stated "I do not see documentation where the physician identified the patient prior to (the administration of) anesthesia in the medical record."</p>	S 552E			

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S 6701		S 6701			

Pennsylvania Department of Health

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S 6701	Continued from page 37 567.1 Principle CHAPTER 567 - ENVIRONMENTAL SERVICES 567.1 Principle The ASF shall have a sanitary environment, properly constructed, equipped and maintained to protect surgical patients and ASF personnel from cross-infection and to protect the health and safety of patients. This REGULATION is not met as evidenced by:	S 6701	The Penn Medicine Radnor Surgery Center, a facility of the Hospital of the University of Pennsylvania (RSC) took prompt steps to discard expired hand sanitizer and expired hand soap, and replace them with unexpired refills upon discovery of these expired products during survey. The staff member was also promptly reeducated by the Manager of the Central Processing department on the proper way to wear a gown for protective purposes. The RSC is taking the following measures to prevent reoccurrence: The staff of the RSC and the Central Processing Department (CPD) will be required to complete re-education on the appropriate use of Personal Protective Equipment (PPE). A process for checking and monitoring expiration dates of hand sanitizer and hand soap is being implemented. - By July 31, 2023, the RSC Administrator and RSC Director of Nursing will meet with the RSC staff and the contracted Central Processing Department (CPD) staff	Completion Date: 07/31/2023 Status: APPROVED Date: 06/23/2023	

Pennsylvania Department of Health

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S 6701	Continued from page 38	S 6701	<p>to re-educate them on the importance of wearing PPE correctly and the proper ways for donning and doffing.</p> <p>- Annual mandatory education is required for all RSC staff and contracted CPD staff on the proper procedure for donning and doffing PPE through the Penn Medicine on line education module "AME: Infection Prevention".</p> <p>- By July 31, 2023, the Supervisor of Penn Medicine Radnor Central Processing Department will run a compliance report to verify that staff have completed the annual mandatory education for the proper procedure for wearing PPE. Any staff that are out of compliance will be required to complete the module before their next working shift. The compliance report will be provided to the RSC Administrator and Director of Nursing.</p> <p>- Signs have been posted on the entrance doors to decontamination areas of CPD alerting staff to the required PPE that must be donned prior to entering.</p>		

Pennsylvania Department of Health

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S 6701	Continued from page 39	S 6701	<p>- Expiration dates for hand sanitizer and hand soap will be monitored by the CPD supervisor or their designee using a monthly checklist that will be placed around the CPD alerting staff to any items that are nearing expiration. This checklist will be implemented by July 31, 2023.</p> <p>- Quarterly environment of care (EOC) rounds in the RSC will be expanded to incorporate the Central Processing Department, starting in July 2023.</p> <p>The RSC will monitor its performance by the following:</p> <p>- Ten (10) weekly audits of PPE and expiration dates of hand sanitizer and hand soap will be conducted by the RSC Administrator or designee to verify compliance.</p> <p>- The RSC Administrator or designee will monitor compliance and notify CPD leadership of any discrepancies.</p> <p>- Auditing of compliance will be monitored by the RSC Administrator or designee until a period of three consecutive months with a compliance rate of 100% is achieved.</p>		

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S 6701	Continued from page 40	S 6701	- Compliance results will be reviewed by the RSC Infection Control Committee and the RSC Quality Assurance Performance Improvement (QAPI) Committee quarterly to demonstrate sustained compliance as part of the ongoing quality assurance and performance improvement activities. Completion date for Plan of Correction is July 31, 2023. Title of person responsible for compliance: RSC Administrator and RSC Medical Director.		

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S 6701	<p>Continued from page 41</p> <p>Based on a review of facility policy, observation, and interview with staff (EMP), it was determined the facility failed to adhere to professionally acceptable standards of practice to ensure a functional and sanitary environment.</p> <p>Findings include:</p> <p>A review of facility policy "Decontamination - Donning and Removing PPE," undated, revealed "PURPOSE: 'Standard Precautions,' are intended to prevent the transmission of infectious agents to healthcare personnel. In accordance with CDC (Centers for Disease Control and Prevention) and AAMI (Association for the Advancement of Medical Instrumentation) guidelines, the use of Personal Protection Equipment (PPE) will be utilized by all Processing staff performing instrument and medical device decontamination and cleaning. PROCEDURE: To ensure staff are appropriately protected from the possibility of exposure from contaminated instruments and/or medical devices, the proper donning and removal of Personal</p>	S 6701			

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S 6701	<p>Continued from page 42</p> <p>Protection Equipment (PPE) must be followed. ...Donning PPE sequence ...3. Fluid Resistant Gown a. Put gown on, ensuring the opening is in the back. b. Secure/tie the gown at the neck and waist."</p> <p>An observation on April 17, 2023, at 10:53 AM in the Endoscope Decontamination Room with EMP5, EMP6, EMP10 and EMP11 revealed PF1, an instrument reprocessing technician, was wearing a fluid resistant gown, untied, with the opening in the front. Further observation revealed PF1 removed the gown, performed hand hygiene, donned a clean gown and re-entered the Endoscope Decontamination Room with the gown opening in the front.</p> <p>An interview conducted on April 17, 2023, at 10:58 AM with PF1 confirmed PF1 routinely wore fluid resistant gowns with the opening in the front during endoscope reprocessing. PF1 stated "I would tie the gown in front at my neck and chest if required to protect my scrubs."</p>	S 6701			

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S 6701	<p>Continued from page 43</p> <p>An interview conducted on April 17, 2023, at 11:00 AM with EMP6 confirmed PF1 was not in compliance with the facility policy for donning PPE. EMP6 further confirmed wearing a fluid resistant gown with the opening in the front during endoscope reprocessing would not provide appropriate protection from the possibility of exposure from contaminated medical devices.</p> <p>_____</p> <p>A review of facility policy "RSC (Penn Medicine Radnor Surgery Center) Infection Control Plan," undated, revealed "OBJECTIVES. The RSC has written policies, procedures, and guidelines to reduce the risk of infection. These policies/guidelines are in accordance with evidence-based standards offered by the Centers for Disease Control and Prevention (CDC), Association of Operating Room Nursing (AORN), the Occupational Safety and Health Administration (OSHA), The Joint Commission (TJC), and Centers for Medicare and Medicaid Services (CMS). GOALS ...The Infection Control Risk Assessment will be</p>	S 6701			

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S 6701	<p>Continued from page 44</p> <p>conducted annually by the Infection Preventionist and presented to the ICC for involvement, review and approval. ...Facility Risks including but not limited to: Hand hygiene compliance. Personal protective equipment compliance."</p> <p>An observation on April 17, 2023, at 9:41 AM in the Endoscopy Pre and Post Procedure area Bay7 with EMP6, EMP10 and EMP11 revealed a bottle of hand sanitizer on the equipment cart. Further observation revealed the expiration date on the hand sanitizer was August 2021.</p> <p>An observation on April 17, 2023, at 10:46 AM in the Endoscope Reprocessing Room with EMP6, EMP10 and EMP11 revealed a soap dispenser above the handwashing sink. Further observation revealed the expiration date on the soap was February 2023.</p> <p>An observation on April 17, 2023, at 10:53 AM in the Endoscope Decontamination Room with EMP6, EMP10 and EMP11 revealed a soap dispenser</p>	S 6701			

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S 6701	<p>Continued from page 45</p> <p>above the handwashing sink. Further observation revealed the expiration date on the soap was February 2023.</p> <p>An interview conducted on April 17, 2023, at 11:00 AM with EMP6 confirmed the hand sanitizer in the pre and post endoscopy area and the hand soap in the Endoscope Reprocessing and Decontamination Rooms was expired. EMP6 further confirmed expired hand sanitizer and soap in endoscopy procedural areas was an infection control risk.</p>	S 6701			



Certified End Page

PENN MEDICINE RADNOR SURGERY CENTER

STATE LICENSE NUMBER: 16751501

SURVEY EXIT DATE: 05/22/2023

**I Certify This Document to be a True and Correct Statement of Deficiencies and
Approved Facility Plan of Correction for the Above-Identified Facility Survey**

A handwritten signature in black ink that reads "Jeane Parisi".

Jeane Parisi
Deputy Secretary for Quality Assurance

A handwritten signature in black ink that reads "Debra L. Bogen MD".

Debra L. Bogen, MD, FAAP
Acting Secretary of Health



THIS IS A CERTIFICATION PAGE

PLEASE DO NOT DETACH

THIS PAGE IS NOW PART OF THIS SURVEY